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EXAMINER

HOBAN, MATTHEW E

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/524,358	Applicant(s) BERGAYA ET AL.	
	Examiner Matthew E. Hoban	Art Unit 1793	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/03/2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37,38,40-62 and 64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37,38,40-62 and 64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
4. Claims 37-38, 40, 42 44, 45-46 and 49-58 rejected under 35 U.S.C. 103(a) as being unpatentable over Abdullah in his publication entitled "An evaluation of accelerate Portland cement as a restorative material" in view of Anderson in 6858074.

5. **Regarding Claim 37:**Abdullah teaches a method of accelerating the setting times of Portland Cement in the field of dentistry and explores the root-end filling capabilities of this system as it is related to biocompatibility, cell leakage, and cell growth on the interface. The purpose of this study was to develop a means by which Portland cement (and a chemically similar MTA composition) could have an accelerated setting time as to not be washed out of the site by saliva thus irritating the oral tissues.

His process as seen in section 2.1, includes combining 10 or 15% CaCl_2 with portland cement, with water mixed with further calcium chloride. Therefore, Abdullah teaches a method of making a Portlandated Portland Cement with 10 or 15% calcium chloride in the solid part and 33 or 50% calcium chloride in the liquid part (the calcium chloride would become hydrated and be dihydrate in the liquid part, CaCl_2 is a dessicant). As was stated in the previous rejection, Portland Cement typically contains 80.9-84% of dicalcium/tricalcium silicates. These parts are then thoroughly mixed.

Throughout the introduction, Abdullah speaks of the advantages of MTA in light of its regenerative abilities concerning tissue. Abdullah specifically talks of MTA and its application to cavity walls with or without pulpal exposure, due to MTA's ability to allow regeneration of both preiradicular and pulpal tissues. His study is specifically to investigate these same properties in the Portland Cement system and to ensure that the addition of the accelerator CaCl_2 does not negatively effect biocompatibility. Abdullah

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shows in Tabl 1 results that are the same as or better than those achieved using normal MTA, thus one of ordinary skill would find the APC used by Abdullah to be highly applicable to all applications of MTA as elucidated by Abdullah.

Abdullah does not teach or suggest the inclusion of calcium carbonate as a filler material or the use of water reducing agents.

However, Anderson teaches that Portland cement can acquire distinct advantages by the inclusion of a high range water reducing dispersants. Advantages are spoken of in Column 4, Lines 44-57, and include the development of strength very quickly as the Portland cement is allowed to hydrate at an increased rate. Furthermore, Anderson gives a list of filler materials for Portland Cements in linves 8-18 of Column 14. He includes calcite, or calcium carbonate in these materials. The addition of fillers is often motivated by cost or by additional properties provided by fillers. The teachings of Anderson are highly relevant to those of Abdullah since both deal with Portland cement and improvements thereon.

As stated previously the phrase "for restoring a mineralized substance" is non-limiting although the composition of Abdullah in view of Anderson would inherantly have a remineralizing effect.

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Regarding Claim 38: Abdullah's mixture is fully mixed. The act of mixture necessarily demands a transmission of high energy to said mixture and the product is necessarily uniform as this is the purpose of mixing.

Regarding Claim 40: Abdullah uses water, which is useful as an amalgam carrier.

Regarding Claim 42: Abdullah expressly teaches that the purpose of using the APC/CaCl₂ system is because MTA has such a long setting time. Thus the setting time of his system must be less than or equal to 2 hours, which is compatible with the handling time of such compositions in the art.

Regarding Claim 44: Abdullah does not teach or suggest the inclusion of zirconia.

Regarding Claims 45-46: Anderson teaches useful proportions of the accelerator compositions in Table A of Column 13. In this table he shows the use of 5-130 ounces per 100 pounds of concrete. As stated later, Anderson uses a water/concrete ratio of roughly .25, meaning 25 pounds of water per pound of concrete. Thus in this scenario, 384 ounces of water are used, meaning that the amount of dispersant is from 1.3- 33.8%. Thus Anderson teaches an overlapping range with all of the instant claims rendering them obvious. Overlapping ranges have been shown to

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present a prima facie case of obviousness. See MPEP 2144.05. Anderson teaches the use of CaCl_2 in the liquid part while Abdullah teaches it in the solid part. Both situations achieve the same result of accelerating the hydration of the silicates in Portland. As stated earlier, Abdullah teaches the accelerator in the liquid part, and when CaCl_2 is solutionized it necessarily forms a dehydrate as it is a dessicant. The anhydrous form is only stable under a low moisture content.

Regarding Claim 49-54: Anderson teaches useful proportions of the dispersant compositions in Table A of Column 13. In this table he shows the use of 2-35 ounces per 100 pounds of concrete. As stated later, Anderson uses a water/concrete ratio of roughly .25, meaning 25 pounds of water pre pound of concrete. Thus in this scenario, 384 ounces of water are used, meaning that the amount of dispersant is from .5- 10% of the liquid part. Thus Anderson teaches an overlapping range with all of the instant claims rendering them obvious. Overlapping ranges have been shown to present a prima facie case of obviousness. See MPEP 2144.05.

Regarding Claim 55-58: Anderson specifically mentions the use of a modified polycarboxylate as a water reducing dispersant (see top of column 3 and column 8, lines 55-60).

6. Claim 41 rejected under 35 U.S.C. 103(a) as being unpatentable over Abdullah in his publication entitled "An evaluation of accelerate Portland cement as a restorative

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material” in view of Anderson in 6858074 as applied to claim 37 above, and further in view of Schwartz in his case study entitled “Mineral Trioxide aggregate: a new material for endodontics”.

As stated previously Abdullah in view of Anderson teaches a method of treating a tooth with a portland cement mixture, including a solid and liquid part including calcium chloride and a water reducing agent.

Abdullah and Anderson are silent as to what teeth this formulation is useful in treating.

Howeve, Schwartz teaches that MTA, the system which Abdullah compares his Portland system to, is useful in various applications including the use on posterior teeth. Case 3, and Figure 5 show the use of MTA in the mandibular left first molar, which is a posterior tooth. Case 4 also details the user of MTA on posterior teeth. Based on the use of MTA in these teeth, the teachings of Abdullah would make it obvious to also use the system of Abdullah in view of Anderson on posterior teeth, since Abdullah's accelerated portland cement is meant to mimic MTA with improved set times.

7. Claims 47-48, rejected under 35 U.S.C. 103(a) as being unpatentable over Abdullah in his publication entitled “An evaluation of accelerate Portland cement as a

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restorative material” in view of Anderson in 6858074 as applied to claim 37 above, and further in view of the MSDS for Calcium Chloride.

As stated previously Abdullah in view of Anderson teaches a method of treating a tooth with a portland cement mixture, including a solid and liquid part including calcium chloride and a water reducing agent.

Abdullah teaches inclusion of calcium chloride in the solid portion of his mixture in an amount from 10 to 15%. Abdullah designates this as simply calcium chloride, but based on the MSDS for this chemical, calcium chloride under normal atmosphere inherently absorbs water (See stability section). Therefore under any normal processing procedure this would be calcium chloride dihydrate. Furthermore, based on these two references one of ordinary skill would find that it is equally useful to include calcium chloride in either the solid or liquid portion and thus using varying amounts of calcium chloride as taught by Anderson and using these same overall proportions in the solid portion would be obvious. Both articles establish that calcium chloride as an accelerant in the setting of portland cement and thus teach that it is a result effective variable in engineering the setting time of the overall composition. Thus routine experimentation in order to find the ideal amount of calcium chloride to provide the desired setting time would be obvious. Upon routine optimization one of ordinary skill would arrive at the same amounts of calcium chloride dihydrate as that of the instant claims.

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8. Claims 43, and 59-61 rejected under 35 U.S.C. 103(a) as being unpatentable over Abdullah in his publication entitled "An evaluation of accelerate Portland cement as a restorative material" in view of Anderson in 6858074 as applied to claim 37 above, and further in view of Turpin in 6451105.

As stated previously Abdullah in view of Anderson teaches a method of treating a tooth with a portland cement mixture, including a solid and liquid part including calcium chloride and a water reducing agent.

Regarding Claim 43: Abdullah in view of Anderson teach the inclusion of calcite but are silent as to the amount of calcite seen as useful to Portland compositions.

However, Turpin teaches that calcium limestone (a form of calcite) is also useful in increasing strength and setting time of portland composites. From his examples using various types of limestone, Turpin teaches improvements in both setting time and strength in composites with 9-44% limestone relative to Portland content. Therefore, one of ordinary skill would see that limestone content in portland compositions is a result effective variable and shows improvement to both set time continuously as content increases. Thus including limestone (calcite) in the instantly claimed proportions would also improve the properties of Abdullah in view of Anderson, since these compositions are also portland compositions. Arrival at the claimed portions are only a matter of routine experimentation since the content of calcite has been established as a result effective variable relative to both setting time and ultimate strength. Therefore, one of ordinary skill would see the results of Turpin as highly relative to those of both Abdullah and Anderson, since Anderson teaches the use of calcite as a filler, but does not explicitly teach desirable ratios of its inclusion.

Regarding Claims 59-61: Abdullah in view of Anderson does not teach the liquid/solid ratios as stated in the claims

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However, upon the inclusion of calcite these ratios would be achieved. For example, the first and second example of APC in Abdullah teach .3 g of water 1g of Portland, where 10 or 15% of calcium chloride is included in the solid part (overall 1.1-1.15g solid). According to the teachings of Abdullah 9-44% of calcite can be included in this composition to improve the strength and setting time of the composition leading to 1.19-1.59 g of solid content to the .3g of water. Therefore the liquid to solid content ranges from .188-.25 + less than 10% based on the amount of water reducing agent added. This range represents an overlapping range with the instant claims.

Overlapping ranges have been shown to present a prima facie case of obviousness. See MPEP 2144.05.

9. Claims 62 and 64 rejected under 35 U.S.C. 103(a) as being unpatentable over Abdullah in his publication entitled "An evaluation of accelerate Portland cement as a restorative material" in view of Anderson in 6858074 as applied to claim 37 above, and further in view of Lopez in 2002/0045678.

As stated previously Abdullah in view of Anderson teaches a method of treating a tooth with a portland cement mixture, including a solid and liquid part including calcium chloride and a water reducing agent.

Regarding Claim 62: Abdullah and Anderson do not teach useful particle sizes as they relate to the dental industry.

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However, Lopez teaches useful ranges of particle sizes of both the cement and filler materials in relation to the dental industry. He states at paragraph 18 that the cement should have a Blaine number of from 4500-4600, where a Blaine of 4500 refers roughly to 4.2 micron particles according to Blaine's equations. He also teaches that filler materials should have prescribed particle sizes of between .1-5 microns at paragraph 26. The teachings of Lopez are highly combinable with the art of reference since Lopez deals with calcium silicate based dental cements, just like Abdullah.

Regarding Claim 64: Abdullah and Anderson do not teach the inclusion of a radiopaque substance as a filler as is relates to the dental industry.

However, Lopez teaches that apatites can be used as filler material to make the substance more radiopaque. The inclusion of radiopaque material in a filling material would be obvious to one of ordinary skill in the art in order to increase x-ray sensitivity and the ability to see fillings after the ceramic has set.

Response to Arguments

10. Applicant's arguments with respect to claim 37 have been considered but are moot in view of the new ground(s) of rejection. The previous rejection is withdrawn since the previous combination of references did not teach application of the portland to a tooth. A new rejection has been made based on Abdullah and other supporting

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references, which is focused on the dental field and the application of portland cement in the field of dentistry.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew E. Hoban whose telephone number is (571) 270-3585. The examiner can normally be reached on Monday - Friday from 7:30 AM to 5 PM EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry Lorengo can be reached on (571) 272-1233. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J.A. LORENZO/

Supervisory Patent Examiner, Art Unit 1793

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